



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No: 37697-0033

Applicant(s): Edward W. MERRILL *et al.* Confirmation No.: 8881  
Serial No.: 09/764,445 Examiner: To be assigned  
Filing Date: January 19, 2001 Group Art Unit: 3738  
Title: RADIATION AND MELT TREATED ULTRA HIGH MOLECULAR  
WEIGHT POLYETHYLENE PROSTHETIC DEVICES

REQUEST FOR INTERFERENCE  
UNDER 37 C.F.R. §1.607(a)

Commissioner for Patents  
Washington, D.C. 20231

Sir:

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Pursuant to 37 C.F.R. §1.607, Applicants hereby request that an interference be declared between the above-captioned patent application and U.S. Patent Nos. 6,017,975 and its continuation 6,242,507 to Saum *et al.* (the '975 patent and the '507 patent respectively). Copies of the '975 and '507 patents accompany this request. Applicants added claims 124-30 to the instant application in a preliminary amendment dated January 19, 2001, and added claims 131-42 by preliminary amendment on August 3, 2001. Applicants also have added claim 143 by way of preliminary amendment, filed herewith.

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Interference  
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**I. Presentation of Counts**

Pursuant to 37 C.F.R. §1.607(a)(2), Applicants present the following proposed count:

**Count 1:**

A process for preparing a medical implant having improved mechanical properties, wherein the method comprises:

irradiating a polyethylene article to form free radicals; and

heating the polyethylene article to a temperature at or above the melting point such that the free radicals can recombine.

**II. Identification of Patent Claims Corresponding to the Proposed Count**

Pursuant to 37 CFR §1.607(a)(3), Applicants hereby identify the claims of the '975 and '507 patents that correspond to the proposed count:

Claims 1-38 of the '975 patent; and

Claims 1-20 of the '507 patent, which are terminally disclaimed over the claims of the '975 patent due to obviousness-type double patenting.

**III. Identification of Application Claims Corresponding to the Proposed Count**

Pursuant to 37 CFR § 1.607(a)(4), (5), Applicants hereby identify the application claims that correspond to the counts:

Presently, claims 124-30 and 43 correspond to the present count. Although claims 131-42 would correspond to the present count, they will be canceled at a later

date without prejudice or disclaimer because they are pending in another application and are subject to another Request for Interference against another patent. Claims 131-42 will be canceled when that other interference is declared. Accordingly, only claims 124-30 and 143 are discussed below.

Support for the claims can be found throughout the application, and exemplary support is set forth below:

CLAIM	SUPPORT
<b>124.</b> A process for preparing a medical implant having an improved balance of wear properties and oxidation resistance comprising the steps of:	Improved mechanical properties are disclosed at Tables 1-4. Bar stock, a type of preform, is disclosed at page 17, lines 1-3. Medical implants are disclosed at page 1, lines 12-15. Oxidation resistance is discussed at page 3, lines 18-19, and the last two lines of page 63.
irradiating a perform of ultrahigh molecular weight polyethylene to form free radicals;	Types of polyethylene, including ultrahigh molecular weight polyethylene, are disclosed at page 32, lines 21-24. Irradiation is disclosed at page 13, last paragraph. Formation of free radicals is discussed at page 14, first paragraph.
annealing the irradiated preform by heating in a substantially oxygen-free atmosphere at a temperature above about 150°C, for a time	Temperatures above the melting point, including those above 150°C, are disclosed at page 20, lines 17-22.

sufficient to recombine substantially all of the free radicals and cross-link the ultrahigh molecular weight polyethylene;	The use of a low oxygen-containing nitrogen atmosphere is disclosed at page 45. Recombination of free radicals is discussed at page 14, first paragraph.
cooling the cross-linked preform while maintaining a substantially oxygen-free atmosphere;	Cooling in a nitrogen atmosphere is disclosed at page 45.
forming a medical implant from the cross-linked preform;	Fabricated articles, such as medical implants, are disclosed at page 29, lines 21-23 and Example 3.
packaging the medical implant in an air-permeable package; and	Packaging is a known requirement of medical implants to protect them from the environment. Most packaging is air permeable.
sterilizing the packaged implant using non-irradiative methods.	Sterilization is a known requirement for medical implants.
<b>125.</b> A process for preparing a medical implant having an improved balance of wear properties and oxidation resistance comprising the steps of:	Improved mechanical properties are disclosed at Tables 1-4. Bar stock, a type of preform, is disclosed at page 17, lines 1-3. Medical implants are disclosed at page 1, lines 12-15. Oxidation resistance is discussed at page 3, lines 18-19, and the last two lines of page 63.
irradiating a preform of ultrahigh molecular	Types of polyethylene, including

weight polyethylene to form free radicals;	ultrahigh molecular weight polyethylene, are disclosed at page 32, lines 21-24. Irradiation is disclosed at page 13, last paragraph. Formation of free radicals is discussed at page 14, first paragraph.
annealing the irradiated preform by heating in a substantially oxygen-free atmosphere at a temperature above about 150°C, to cross-link the ultrahigh molecular weight polyethylene;	Temperatures above the melting point, including those above 150°C, are disclosed at page 20, lines 17-22. The use of a low oxygen-containing nitrogen atmosphere is disclosed at page 45. Cross-links are disclosed at page 14, second paragraph.
cooling the cross-linked preform while maintaining a substantially oxygen-free atmosphere;	Cooling in a nitrogen atmosphere is disclosed at page 45.
forming a medical implant from the cross-linked preform.	Fabricated articles, such as medical implants, are disclosed at page 29, lines 21-23 and Example 3.
<b>126.</b> A medical implant prepared according to the process of claim 124.	See discussion for claim 124.
<b>127.</b> A medical implant prepared according to the process of claim 125.	See discussion for claim 125.
<b>128.</b> A cross-linked ultrahigh molecular weight polyethylene having a swell ratio of less than about 5 and an oxidation level of less	Cross-linked ultrahigh molecular weight polyethylene having improved mechanical properties are disclosed at

than about 0.2 carbonyl area/mil sample thickness after aging the ultrahigh molecular weight polyethylene at 70°C, for 14 days in oxygen at a pressure of about 5 atmospheres.	Tables 1-4.
<b>129.</b> A medical implant comprising the ultrahigh molecular weight polyethylene of claim 128.	Medical implants made from cross-linked ultrahigh molecular weight polyethylene having improved mechanical properties are disclosed at page 1, lines 12-15 and Table 1-4.
<b>130.</b> A process for preparing a medical implant having an improved balance of wear properties and oxidation resistance comprising the steps of:	Medical implants made from cross-linked ultrahigh molecular weight polyethylene having improved mechanical properties are disclosed at page 1, lines 12-15 and Table 1-4. Oxidation resistance is discussed at page 3, lines 18-19, and the last two lines of page 63.
irradiating a preform of ultrahigh molecular weight polyethylene to form free radicals;	Types of polyethylene, including ultrahigh molecular weight polyethylene, are disclosed at page 32, lines 21-24. Irradiation is disclosed at page 13, last paragraph. Formation of free radicals is discussed at page 14, first paragraph.
annealing the irradiated preform by heating at a temperature above about 150°C, for a time sufficient to recombine substantially all of the	Temperatures above the melting point, including those above 150°C, are disclosed at page 20, lines 17-22.

free radicals and cross-link the ultrahigh molecular weight polyethylene;	Cross-links are disclosed at page 14, second paragraph.
cooling the cross-linked preform;	Cooling is disclosed at page 45.
forming a medical implant from the cross-linked preform;	Fabricated articles, such as medical implants, are disclosed at page 29, lines 21-23 and Example 3.
packaging the medical implant in an air-permeable package; and	Packaging is a known requirement of medical implants to protect them from the environment. Most packaging is air permeable.
sterilizing the packaged implant using non-irradiative methods.	Sterilization is a known requirement for medical implants.
<b>143.</b> A process for preparing a medical implant having improved mechanical properties, wherein the method comprises:	Medical implants made from cross-linked ultrahigh molecular weight polyethylene having improved mechanical properties are disclosed at page 1, lines 12-15 and Table 1-4.
irradiating a polyethylene article to form free radicals; and	Types of polyethylene, including ultrahigh molecular weight polyethylene, are disclosed at page 32, lines 21-24. Irradiation is disclosed at page 13, last paragraph. Formation of free radicals is discussed at page 14, first paragraph.
heating the polyethylene article to a	Temperatures above the melting point

temperature at or above the melting point such that the free radicals can recombine.	are disclosed at page 20, lines 17-22. Recombination of free radicals is disclosed at page 14, first paragraph.
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**IV. Compliance with 35 USC § 135(b)**

Claims 124-42 were copied prior to the one-year anniversary of the issuance of the '975 patent and its obvious counterpart '507 patent. Moreover, original claim 36 and its dependents, for example, correspond to the count and were pending well before the one-year anniversary of the issuance of the '975 and '507 patents. Accordingly, the requirements of 35 USC § 135 have been met.

**V. Statement under 37 CFR § 1.608(a)**

The undersigned attorney of record hereby states that there is a basis for which applicant is entitled to judgment relative to patentee. Applicants' earliest effective filing date is February 13, 1996 from U.S. Serial No. 08/600,744, which is almost five months earlier than the filing of patentee's first provisional application, filed July 9, 1996. Applicants' specification, as well as the priority '744 application, fully support the claims. Accordingly, applicants submit that (i) an interference should be declared, (ii) applicants should be deemed the senior party, (iii) applicants be afforded the benefit of all priority applications, and (iv) applicants enjoy the presumption of first invention under



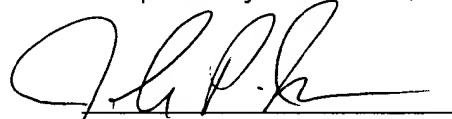
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37 CFR § 1.657. Applicants therefore submit that they have demonstrated an entitlement to judgment and that the interference should be declared in due course.

December 30, 2002

HELLER EHRMAN WHITE & McAULIFFE  
1666 K Street, N.W., Suite 300  
Washington, D.C. 20006  
Tel: 202-912-2000  
Fax: 202-912-2020

Respectfully submitted,

  
John P. Isacson  
Reg. No. 33,715



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